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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/147,801	03/11/1999	BO NIKLASSON	REF/29713/NI	2230

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EXAMINER	
MOSHER, MARY	
ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 02/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/147,801	NIKLASSON, BO	
	Examiner	Art Unit	
	Mary E. Mosher, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 September 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,7,9,11,15,16 and 18* is/are pending in the application.

4a) Of the above claim(s) *1-3 and 5* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *4,7,9,11,15,16 and 18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

As indicated in the attached Interview Summary, allowable claims were proposed by the Examiner, and an assistant at the representative's law firm indicated approval of the client. However, since no registered attorney returned calls requesting authorization for an Examiner's amendment, the claims remain as presented in the 9/28/2004 amendment.

Election/Restrictions

Claims 1-3 and 5 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 10/23/2000.

Claim Rejections - 35 USC § 112

Claims 4, 7, 9, 11, 15, 16, 18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant is requested to point to support in the specification for the new claim limitations "wherein said antigenic fragment is not amino acid sequence VLRTYNSSSP." The examiner fails to find anything in the original specification which reasonably communicates the concept of "every antigenic fragment of SEQ ID NO 4 except VLRLTYNSSP." This affects the dependent claims.

In addition, claim 18 presents an additional "written description" issue, in that it requires a subunit of a virus which has in its genome a sequence at least 75% identical to SEQ ID NO: 1. The specification does not disclose any characteristics of any subunit of a virus. The specification reasonably communicates possession of virions or virus-like particles and three virus isolates, but the specification provides no information on the physical or chemical characteristics of subunits from these viruses. Therefore, it is concluded that the specification does not reasonably convey possession of the subunits required in claim 18. Applicants argue that viral subunits are known components of viruses in the same way that a wheel is a known component of a bicycle. However, viral subunits are complex biomolecules, and their structure and properties are much more unpredictable than a bicycle wheel. The courts have clearly articulated a standard for written description requiring a precise definition, such as by structure, formula, chemical name, or physical properties, not a mere wish or plan for obtaining the desired material. In this case, the specification articulates a wish for a viral subunit, without reasonably communicating that applicants possessed any knowledge of the structure, formula, chemical name, or physical properties of any viral subunit. Therefore this rejection is maintained.

Claims 4, 7, 9, 11, 15, 16, 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 4 is indefinite in reciting a sequence without a SEQ ID identifier. The dependent claims do not cure this deficiency.

Claims 7, 9, 11, 15, 16, and 18 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a diagnostic kit comprising SEQ ID NO: 4 or an antigenic fragment of SEQ ID NO 4 wherein the antigenic fragment reacts with antibodies specifid to Ljungan picornavirus, and for an immunogenic composition comprising SEQ ID NO:4 or a fragment of SEQ 4 which induces or reacts with antibodies specific to Ljungan picornavirus, does not reasonably provide enablement for the full scope of products or methods claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

In regard to diagnostic claims, applicant argues that infection with a virus will cause the production of antibodies directed against SEQ ID NO:4, and the presence of such antibodies can be determined using SEQ ID NO: 4. Publications obtained by the Examiner indicate that SEQ ID NO:4 is a large fragment of a major capsid protein. Therefore the assertions of diagnostic utility for SEQ ID NO:4 are supported by evidence. The specification, however, provides no teachings of how to diagnose infection using antigenic fragments which do not immunologically cross-react with the virus. Therefore enablement of fragments is limited to is fragments which react with antibodies specific to Ljungan picornavirus.

In regard to vaccine and therapy claims, applicant argues that an immune response raised against an antigenic component of an infectious agent will, to some extent, have a beneficial effect in preventing or treating a subsequent viral

infection. This is not always the case, as pre-existing antibodies sometimes exacerbate rather than ameliorate subsequent infections (e.g. Feline Infectious Peritonitis Virus, Dengue Virus). However, in the case of this picornavirus, the examiner agrees that a pre-existing immune response against the capsid segment SEQ ID NO:4 may be of some benefit in ameliorating infection, and is very likely to be useful for making antiviral antibodies. Therefore claims directed to immunogenic compositions would be allowable. However, the specification does not teach how to prevent disease or how to treat existing disease absent undue experimentation, and therefore it is maintained that vaccines and therapeutic compositions are not enabled.

Allowable Subject Matter

The following claims would be allowable:

Claim 20 (new). An isolated protein comprising SEQ ID NO:4 or an antigenic fragment of SEQ ID NO:4, wherein the antigenic fragment induces or reacts with antibodies specific to Ljungan picornavirus.

Claim 21 (new). An immunogenic composition comprising the protein of claim 20.

Claim 22 (new). The immunogenic composition of claim 20, further comprising an adjuvant.

Claim 23 (new). An isolated antibody induced by or reactive with SEQ ID NO:4 or an antigenic fragment thereof, wherein the antibody is specific to Ljungan picornavirus.

Claim 24 (new). A diagnostic kit comprising the protein of claim 20 or the antibody of claim 23, and diagnostic reagents.

Claim 25 (new). A method of inducing an immune response comprising administering the composition of claim 21.

Claim 26 (new). The isolated protein of claim 20, wherein the protein which comprises an antigenic fragment of SEQ ID NO:4 is at least 75% homologous to SEQ ID NO:4.

The following is a statement of reasons for the indication of allowable subject matter: Later publications substantiate a number of the assertions made in the specification. The full sequence of the 145SL polyprotein is now known, see NCBI locus AAM46801 (Genbank AF327922.1). Comparison of the polyprotein with SEQ ID NO:4 indicates that SEQ ID NO 4 corresponds to residues 322-502 of the polyprotein, and Johansson et al (Journal of Virology 76:8920-2930, 2002) indicates that this region constitutes about 3/4 of the sequence of the VP3 capsid protein. Since the VP3 protein is a major antigen in picornaviruses, the specification is most likely correct in asserting that SEQ ID NO:4 and its fragments are useful for at least making and detecting antibodies that recognize Ljungan virus. Ljungan virus has become recognized in the art as a distinct species of picornavirus, and virus isolates described in the specification are now recognized in the art as prototype of the species. See for example Lindberg et al (Virus Research 85:61-70, 2002), the abstract by Hughes (Infection, Genetics, and Evolution 4:143-152, 2004, abstract only cited), and

Table 1 of Johansson et al. For these reasons, claims to immunologically useful compositions and methods are now seen as enabled by the original disclosure.

In regard to the suggested claim language, the specification does not provide ipsis verbis support for the claims, but literal support is not required. The specification clearly communicates that applicants possessed Ljungan virus and also possessed SEQ ID NO:4. The specification clearly communicates the concept of antibodies directed against structural proteins of this virus, and the concept of immunogenic and diagnostic use, see for example page 18. The specification also communicates indirectly the concept of immunological materials specific to this new type of virus. For example, the specification discusses a variety of picornavirus species suspected in causing human disease on pages 1-3, describes use of sera from diseased humans to screen and identify novel viruses on page 4, and provides a working example of immunological distinction of Ljungan virus from TEMV and ECMV on page 8. Specification pages 18-19 also discuss "negative reference samples" in diagnostic kits. Taken as a whole, this is all seen as support for the claim language regarding materials "specific to Ljungan picornavirus."

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher, Ph.D. whose telephone number is 571-272-0906. The examiner can normally be reached on M-T and alternate F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

2/10/05

MARY E. MOSHER
PRIMARY EXAMINER
GROUP ~~1800~~ 1600

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with FILL IN on FILL IN.

The application has been amended as follows:

The claims have been amended as shown on the attached listing of claims.

The following is an examiner's statement of reasons for allowance:

Later publications substantiate a number of the assertions made in the specification. The full sequence of the 145SL polyprotein is now known, see NCBI locus AAM46801 (Genbank AF327922.1). Comparison of the polyprotein with SEQ ID NO:4 indicates that SEQ ID NO 4 corresponds to residues 322-502 of the polyprotein, and Johansson et al (Journal of Virology 76:8920-2930, 2002) indicates that this region constitutes about 3/4 of the sequence of the VP3 capsid protein. Since the VP3 protein is a major antigen in picornaviruses, the specification is most likely correct in asserting that SEQ ID NO:4 and its fragments are useful for at least making and detecting antibodies that recognize Ljungan virus. Ljungan virus has become recognized in the art as a distinct species of picornavirus, and virus isolates described in the specification are now recognized in the art as prototype of the species. See for example Lindberg et al

(Virus Research 85:61-70, 2002), the abstract by Hughes (Infection, Genetics, and Evolution 4:143-152, 2004, abstract only cited), and Table 1 of Johansson et al. For these reasons, claims to immunologically useful compositions and methods are now seen as enabled by the original disclosure.

In regard to the claim language, the specification does not provide ipsis verbis support for the claims, but literal support is not required. The specification clearly communicates that applicants possessed Ljungan virus and also possessed SEQ ID NO:4. The specification clearly communicates the concept of antibodies directed against structural proteins of this virus, and the concept of immunogenic and diagnostic use, see for example page 18. The specification also communicates indirectly the concept of immunological materials specific to this new type of virus. For example, the specification discusses a variety of picornavirus species suspected in causing human disease on pages 1-3, describes use of sera from diseased humans to screen and identify novel viruses on page 4, and provides a working example of immunological distinction of Ljungan virus from TEMV and ECMV on page 8. Specification pages 18-19 also discuss "negative reference samples" in diagnostic kits. Taken as a whole, this is all seen as support for the claim language regarding materials "specific to Ljungan picornavirus." Therefore, the specification as filed is concluded to adequately describe and enable the invention as now claimed.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably

accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher, Ph.D. whose telephone number is 571-272-0906. The examiner can normally be reached on M-T and alternate F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

1/14/05

Claim Listing.

Claims 1-19 (cancelled).

Claim 20 (new). An isolated protein comprising SEQ ID NO:4 or an antigenic fragment of SEQ ID NO:4, wherein the antigenic fragment induces or reacts with antibodies specific to Ljungan picornavirus.

Claim 21 (new). An immunogenic composition comprising the protein of claim 20.

Claim 22 (new). The immunogenic composition of claim 20, further comprising an adjuvant.

Claim 23 (new). An isolated antibody induced by or reactive with SEQ ID NO:4 or an antigenic fragment thereof, wherein the antibody is specific to Ljungan picornavirus.

Claim 24 (new). A diagnostic kit comprising the protein of claim 20 or the antibody of claim 23, and diagnostic reagents.

Claim 25 (new). A method of inducing an immune response comprising administering the composition of claim 21.

Claim 26 (new). The isolated protein of claim 20, wherein the protein which comprises an antigenic fragment of SEQ ID NO:4 is at least 75% homologous to SEQ ID NO:4.